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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,305	10/24/2003	William F. Crismore	7404-572/BMID-9738RE-DIV3	1452

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,305	Applicant(s) CRISMORE ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-103 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 39-103 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/21/05, 3/21/05, 10/12/03</u> | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 55, 70, 81 and 93 are vague and indefinite as to the placement of the opaque portion.

Claims 42, 58, 73, 84 and 96 are vague and indefinite what is intended by a color of the opaque to contrast with the body fluid. The term contrast is relative and what one person believes is a contrast may not be what another believes is a contrasting color.

Claims 43, 59, 74, 85 and 97 are not clear where the opaque portion extends.

Claims 44, 60, 75, 86 and 98 are not clear which edge (e.g. right or left) is intended.

Claims 46, 62, 87 are not clear what the opaque portion is aligned with.

Claims 48, 68 and 99 are not clear what the relationship is between the opaque and visualization portions.

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39-40, 42-56, 58-71, 73-82, 84-94 and 96-103 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Poto et al. (USP 5,728,352) or Douglas et al. (USP 5,84,691).

In light of the above 35 USC 112 second paragraph issues, the relationship between the opaque and transparent portions are not clear. For the purposes of

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examination, the claims will be interpreted as having transparent/translucent regions and opaque regions.

Poto et al. teach a test strip(12) having outer edges that mate with two lateral edge guides(36) and angled fore edge tab(40) have been read on the claimed "outer edge". Column 6 lines 50+ teach the appropriate dry chemistry to test for common analytes such as cholesterol on strip(12) and has been read on the claimed "test reagent". The blood sample is deposited on test spot area(20) which has been read on the claimed "application port". Reading aperture(46) has been read on the claimed "visualization portion". The remainder of the strip(12) has been read on the claimed "opaque portion".

Douglas et al. teach in the abstract a multilayer colorimetric reagent test strip for measuring glucose concentrations in whole blood. Column 10 lines 26-37 teach opaque and transparent regions of the device. Column 11 lines 6-29 teach a vent.

Claims 39-103 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Columbus (USP 4,323,536), Terry (USP 5,229,299), Churchouse et al.(USP 5,310,525), Cox (USP 5,366,902).

Columbus(USP 4,323,536) teach a capillary device(10) where surface elements(30,32,34 and 36) are spaced "S" width apart from the support promoting capillary flow between the surfaces. Vent aperture(50)is taught. Layer(56) is taught as being opaque. The sample is placed in aperture(46). Column 4 lines 46+ teach a reagent composition.

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Terry teach a test device(10) comprising a strip of reagent impregnated paper(13) formed between two sheets of transparent plastic(11,12). Opening(15) is the sample application port. Column 5 lines 15-17 teach sheet(11) may be opaque. Column 3 lines 33-59 teach the plastic sheets maybe transparent or translucent.

Churchouse et al. teach s device comprising an impervious container(10,12,14) with a fluid entry aperture(20) and a detection layer(16) containing reagents. Column 2 lines 57-68 teach the layers maybe either transparent or translucent. Column 3 lines 1-13 teach use of an opaque layer.

Cox teach a device(1) comprising a rim(4) that assists transferring the sample into cup(2). Capillary bore(3) is in communication with the cup(2) and the chamber is vented through axial bore(8). Reagent pad(9) reacts with the sample to provide a colorimetric result of the analytes. Columns 4-5 lines 47-15 teach transparent or translucent layers and an opaque region.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
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